The association of electrical equipment
and medical imaging manufacturers
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National Electrical Manufacturers Association

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EPA Region 9 on Detail to OCSPP/OPPT/ECRMD/Existing Chemicals Risk Mgmt Branch #1
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Sent via email to: Sheehan.Eileen@epa.gov and Parsons.Douglas@epa.gov

RE: Proposed Regulation of N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP)

Dear Ms. Sheehan and Mr. Parsons:

The National Electrical Manufacturers Association (NEMA) represents nearly 325 electrical equipment and medical imaging manufacturers that make safe, reliable, and efficient products and systems in seven industrial sectors. NEMA Member companies represent over 370,000 American manufacturing jobs in more than 6,100 facilities. Worldwide annual sales of products in the NEMA scope exceed $140 billion.[1]

NEMA and its Members thank you and your Agency colleagues for meeting with us on March 10, 2021 and giving attention to our views on the Agency's actions concerning NMP. We offer the comments below as a follow-up to that discussion.

At the March meeting, NEMA Members expressed disagreement with the finding that NMP poses an unreasonable risk to human health or the environment in the conditions of use applicable to the electroindustry. In response, EPA requested additional information about industrial hygiene procedures and data on potential dermal exposure. These comments contain NEMA response to that request.

Much of what is presented herein relate to NMP as used in the magnet wire industry because EPA has visited two NEMA Member magnet wire facilities, NEMA previously provided comments on NMP uses in magnet wire, which constitutes one of the primary applications of this chemical. However, we want to be clear that we are asking for regulatory relief on additional products/articles and uses; please see Table 3 (in the appendix) for detailed summary.

[1] For more information, please visit: https://www.nema.org/.

In general, we urge EPA to exercise its statutory authority to grant appropriate exemptions from restrictions on NMP. If unable to provide permanent regulatory relief, the Agency should grant reasonable and sufficient time for finding and implementing a suitable alternative.

Summary of NEMA Comments

1. NMP Does Not Pose Unreasonable Risk
2. EPA Determination Flawed
3. EPA Must Grant a Critical Use Exemption
4. Call for Eight-Year Phase-Out Period
5. EPA Must Grant Additional Exemptions
6. Partnership Needed for Effective Chemical Management

NMP Does Not Pose Unreasonable Risk

For EPA to make a determination of risk when evaluating a chemical, it must analyze both hazard *and exposure*.[2] NEMA Members have endeavored to demonstrate for the Agency that little, if any, exposure to NMP occurs during the manufacturing process or through the use of NEMA Member products through site visits and previous comments. This section reiterates the basis of NEMA's position on this issue while also providing the additional information the Agency requested during the March 10 meeting.

Typical NMP Uses in the Electroindustry

Products manufactured through the use of NMP provide substantial benefits to nearly every major manufacturing sector including transportation, energy, communications, defense, and healthcare. A representative sample of products made possible by the qualities unique to NMP include medical devices, hospital infrastructure, military defense hardware, electric vehicles, wind turbines, lighting, computers, cellular phones, batteries, motors, transformers, and semiconductor fabrication equipment.

In the electroindustry, NMP functions as a solvent and diluent in industrial coatings and composites and is also an important component of coatings and composites, the electroindustry incorporates the chemical into a variety of processes and manufactured articles. As a solvent, NMP is used during manufacturing, remanufacturing, and repair processes to remove protective (conformal) coatings, adhesives, and gaskets. NMP is one of the only solvents commercially available that can dissolve polyamide-imides (PAI) and polyimides (PI) resins (polymeric oligomer). Using chemical solvents to remove coatings, adhesives, and gaskets is less damaging to components than mechanical or thermal methods.

NMP functions as a component of multiple other materials including paints and coatings, lubricants, plastic resins, and adhesives.

[2] The mandate to evaluate both hazard and exposure is stated repeatedly throughout the Lautenberg Chemical Safety Act.

NMP is also used in a variety of other critical manufacturing processes, including solder processes in solder paste and flux materials. Solder paste and flux are critical to soldering applications.

These uses are essential to the production of magnet wire (also known as "winding wire"). Magnet wire is an insulated electrical conductor, usually based on copper or aluminum wire, wound into a coil and energized, creating an electro-magnetic field that is necessary for almost all generation and many uses of electricity.

Magnet wire plays an important role in areas of energy transformation and renewable energy through its use in transformers, motors (including electrical servo and spindle motors), and generators. Wind turbine generators also rely on magnet wire.

Magnet wire also plays an important role in medical and hospital equipment, pharma equipment, and infrastructure. Precision small diameter magnet wire is also used in implantable and single use medical devices.

In addition, magnet wire has a wide range of applications in communications technology, such as coils in computers, cellular phones, video games and televisions.

Lastly, magnet wire is inherent in defense hardware, electric vehicles, consumer packaging equipment, semiconductor fab equipment, and machine tool equipment.[3]

Physical Nature of NMP

To understand why NMP poses minimal risk of exposure, it is necessary to understand the physical nature of the chemical. Sigma-Aldrich provides a concise summary of the physical properties and uses of NMP: [4]

> NMP is an effective solvent for organic and inorganic compounds. Tertiary amides in H-bond basicity are decreased by bulky substituents on carbon than bulky substituents on nitrogen. It is also an effective solvent for the decarbonylation of aldehydes. It exhibits as reagent and amidines formed from NMP exist as amidine-enediamine tautomers. As cosolvent it has ability to enhance the reactivity of other reagents.

Scientific treatises on the chemical state that "NMP is a very slow evaporating solvent"[5] and that "low vapor pressure of NMP (0.342 mm Hg at 25°C) limits the saturated vapor concentration to about 450 ppm at room temperature…[and]…that hydrolysis in air at relative humidities of 40–60% can reduce maximum concentrations to approximately 130 ppm."[6]

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[3] For more information, please see the "Use of NMP in Electroindustry Manufacturing Substantially Benefits Health and Public Safety" section of these comments; Please also see Table 3.
[4] https://www.sigmaaldrich.com/.
[5] Fluorinated Coatings and Finishes Handbook, Laurence W. McKeen, 2016; https://www.sciencedirect.com/book/9780323371261/fluorinated-coatings-and-finishes-handbook.
[6] Semiconductor Safety Handbook, David G. Baldwin, Michael E. Williams, 1998; https://www.sciencedirect.com/book/9780815514183/semiconductor-safety-handbook.

Minimal Risk to Human Health

The unique properties of NMP result in minimal risk to human health, specifically, because of the chemical's low vapor pressure. Scientific studies have established that "the potential inhalation exposure hazard is low." [7] Although it is recognized that NMP can be absorbed through the skin, studies show that "butyl-rubber gloves provided excellent protection under all test conditions…"[8] Therefore, it is clear that NMP exposures in the workplace can be prevented with proper industrial ventilation and with readily available personal protective equipment (PPE).

NEMA Members take great care to prevent exposure during the manufacturing process and to consumers. NEMA contends therefore that the impact of NMP on human health, accounting for potentially exposed or susceptible subpopulations, is virtually non-existent.

EPA Manufacturing Facility Site Visits

On October 4, 2017, NEMA facilitated an EPA visit to the manufacturing facilities of the two Member companies: Rea Magnet Wire Company Inc. and Essex Group, Inc. Located in Fort Wayne, IN, both companies use NMP in the manufacture of magnet wire. EPA summarized their visit:

> On October 4, CCD and RAD visiting two sites that use N-methylpyrrolidone (NMP) in magnet wire manufacturing in Fort Wayne, IN (Rea Magnet Wire Company Inc. and Superior Essex Fort Wayne Magnet Wire Plant). The visit was arranged by the National Electrical Manufacturers Association (NEMA), as a follow up to their public comments of February 14, 2017. The day before the visit, CCD and RAD met with a NEMA representative. 'During the site visits, plant managers and corporate representatives presented an overview of their production process, the use of NMP, how workers handle NMP, the personal protective equipment and engineering controls in place, available monitoring data, the emissions and releases of NMP, and disposal of hazardous waste containing NMP.'[9]

Highlights of the visit included extensive environmental overviews by company staff of the various federal and state environmental permits in place. The employees also provided a safety review which included details about PDS-IDEM Monitoring and Safety Management Systems (SMS). The SMS includes:

- Safety Data Sheet (SDS) Management
- Product SDS Authoring
- Chemical Inventory Management

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[7] *Id.*
[8] *Id.*
[9] US EPA Site Visit Summary Document, regarding "Chemical Use Outreach Visit with Magnet Wire Manufacturing Plants to discuss NMP use" October 4, 2017.

- Global Harmonizing Standards
- Hazardous Communication (HAZCOM) Standards
- Industrial Hygiene
- Personal Protective Equipment (PPE) Standard
- Hazardous Waste Operations and Emergency Response (HAZWOPER)
- Department of Transportation Hazardous Materials (DOT Hazmat)
- Ignitable Liquid Fire Management
- Fire Suppressant Management

During the visit, the hosts presented the practical and effective engineering controls, administrative procedures, PPE standards and practices, spill prevention and cleanup, and recordkeeping requirements in place to reduce unreasonable risk during the use of NMP. The visit concluded with plant tours and question and answer sessions. The principal missive for EPA staff was that the nature of the chemical, coupled with the adequate safety procedures, ensure that NMP poses little risk of exposure. At the conclusion of the visit, EPA visiting staff indicated that they found NMP to be well-managed throughout the entirety of the magnet wire manufacturing operation.

Industrial Hygiene Procedures

The magnet wire industry has long utilized NMP as a solvent and diluent in high-performance magnet wire enamels, thinners, and cleaners. This application of NMP serves as a representative example of the industrial hygiene procedures employed within the electroindustry to prevent hazards and ensure worker safety. EPA was able to witness these practices during the aforementioned site visits. This section serves to further illustrate the issue.

In the magnet wire industrial process, a copper or aluminum wire is routed through an applicator of solvent-based enamel coating. The size of applicator may vary throughout the industry, but most contain ½ – 1 gallon of coating, which contains at most 80-85% concentration of NMP. NMP does not react with the other ingredients in this coating but is simply mixed in to facilitate the smooth application of the enamel. NMP's role here is critical since rough application of the enamel would result in a blistered film and ultimately cause failure of the magnet wire to create the electro-magnetic field.

After leaving the applicator, the wet-coated wire passes through a curing oven where the NMP evaporates from the mixture, leaving a thin film of cured polymer on the wire. Magnet wire usually gets several coats of enamel, each followed by a pass through the curing oven. It is important to note here that the polymer applicator and curing oven are completely enclosed and there is no human exposure to NMP during this process. Any vapor emitted during application moves directly into the curing oven wherein at least 90% of the NMP combusts[10]. Depending on the type of oven, operating temperatures range from 800 – 1400°F degrees.

Upon exiting the curing oven on its final pass, the newly-enameled wire is given a lubricant coating to aid in coil winding by the customer. The finished article contains only trace amounts of NMP due to the curing process previously described.

[10] AP 42, Fifth Edition, Volume I Chapter 4: Evaporation Loss Sources (4.2.2.3).

In addition to the application and curing process, another facet to magnet wire manufacturing is maintenance cleaning. Enameling equipment is bathed in agitated tanks of NMP. These tanks range in size but are commonly around 50 gallons. This process is also completely enclosed while equipment is cleaned. When the cycle completes, the operator retrieves the equipment by opening the tank lid, which prompts the basket to rise up and drain the NMP back into the tank. Emissions consist of evaporation from the NMP bath and from the cleaned parts removed from the bath. Note that NMP evaporation is limited by NMP's low vapor pressure.

Human exposure to NMP is controlled through the use of PPE such as gloves, aprons, and goggles, as well as engineering controls.[11] And as noted earlier, gloves and aprons made from readily available polymers such as butyl-rubber provide adequate protection from skin exposures. As previously mentioned, both the application and curing and cleaning processes are completely enclosed and ventilated. Due to regular, widespread industry application of these preventive safety measures, use of NMP as a solvent for cleaning and degreasing operations in magnet wire facilities does not present an 'unreasonable risk' to workers under these COUs, as per TSCA Section 6(b)(4)(A).

The EPA has estimated annual emissions from a magnet wire operating line without an incinerator at 84 mg per year,[12] however, most operating lines today do have incinerators, which further reduces emissions. NMP losses to the environment from magnet wire ovens are reduced dramatically by routing solvent gases through the magnet wire oven combustion process. Modern magnet wire ovens are known to capture and control solvent vapors at efficiency 95% or better, so actual NMP airborne losses are much lower. Furthermore, NMP losses to the environment are limited by strict controls on air emissions through the combustion process.

There are also emissions of NMP vapors during equipment cleaning, but this is limited by NMP's low vapor pressure. Emissions are further limited through simple management techniques such as keeping cleaning tanks covered, other than when adding and removing items to be cleaned.

For further information on emissions and emission allowances, we refer EPA to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Surface Coating of Miscellaneous Metal Parts and Products.[13] This regulation enforces emission standards for metal parts and products surface coating operations located at major sources of hazardous air pollutants (HAP). The regulation implements section 112(d) of the Clean Air Act (CAA) by requiring operations to meet HAP emission standards reflecting the application of the maximum achievable control technology (MACT). The regulation was promulgated to protect air quality and promote the public health by reducing emissions of HAP from facilities. Although NMP is not named specifically in the regulation, facilities' safe practices under this regulation apply to the handling of NMP as well. Manufacturers' procedures and personal protective equipment ensure that NMP emissions are controlled and there is minimal chance for dermal exposure from vapor.

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[11] For detailed information about typical PPE employed throughout this manufacturing process, please see FUJIFILM Holdings America Corp. January 21, 2020 comments to Docket ID # EPA-HQ-OPPT-2019-0236.
[12] AP 42, Fifth Edition, Volume I Chapter 4: Evaporation Loss Sources (4.2.2.3)
[13] CFR-2015-title40-vol13-part63-subpartMMMM.pdf.

Dermal Exposure Data

At the March 10, 2021 meeting, EPA requested information about dermal exposure. NEMA Members report that they have little if any data on dermal exposure of NMP because this risk is managed by basic industrial hygiene protocols. Absorption of liquid NMP through skin is controlled in industry by simple work practices, such as preventing workers from allowing their hands or other dermal surfaces to come in direct contact with NMP. This is achieved both through safety protocols, equipment-use protocols, and PPE (all of which are described in detail elsewhere in this document). Such work practices and PPE are routine in industry.
As for absorption of NMP vapors through skin, it should be noted that product literature for NMP is far from uniform in stating that skin absorption of NMP vapors is indeed a potential source of substantive NMP loading to the human body.

Despite the uncertainty regarding genuine risk from skin absorption of NMP vapors, NEMA Members employ the highest safety and protective standards. Human health and safety remain the highest priority considerations for NEMA Members.

Minimal Risk to Consumers

In previous sections, NEMA has contended that NMP does not present unreasonable risk to workers during the manufacturing process; here we would like to address public safety considerations. As used in electroindustry articles, NMP does not present an unreasonable risk to health, including to potentially exposed and susceptible subpopulations such as consumers.

As discussed earlier, EPA must evaluate both hazard *and exposure* in making a risk determination.[14] While these comments do not review the health effects of NMP, its *exposure potential is very low*, ensuring that any risk associated with the use is not 'unreasonable.'

Most of the uses of NMP would not foreseeably result in consumer exposure because these parts are inaccessible to users of the end product, or part of systems that consumers to which consumers do not have access. Even for components where contact with consumers is possible, exposure is minimal because the finished product contains only trace amounts of NMP due to the curing process previously described.

Minimal Risk to Environment

Liquid or solid waste is handled in compliance with the Resource Conservation and Recovery Act. Furthermore, EPA has recognized that NMP has low hazard for ecological receptors and is quite biodegradable, thus having low persistence if minimally released into aquatic or terrestrial environments.[15]

[14] The mandate to evaluate both hazard and exposure is stated repeatedly throughout the Lautenberg Chemical Safety Act.
[15] U.S. EPA, TSCA Work Plan Chemical Risk Assessment, N-Methylpyrrolidone: Paint Stripper Use.

Conclusion

NEMA and its Members believe this additional data shows that little, if any, exposure to NMP occurs during the manufacturing process or through the use of NEMA Member products. When making a determination of risk when evaluating a chemical, EPA must analyze both hazard *and exposure*.[16] Therefore, we expect EPA to change its previous determination on the COUs for which it found risk for NMP.

EPA Determination Flawed

Another reason EPA should change its previous risk determination on the 26 NMP COUs stems from the process the agency used in analyzing data to make its determination. In its comments to EPA, NEMA explained that "the polymer applicator and curing oven are completely enclosed and there is no human exposure to NMP during this process."[17] NEMA also informed EPA that "[h]uman exposure to NMP is controlled through the use of personal protection equipment such as gloves, aprons and goggles as well as engineering controls."[18] It is also important to note that EPA characterized the strength and reliability of NEMA's data as "high," as characterized by the risk evaluation and evidenced in EPA's supplemental document evaluating data quality.[19]

Despite this information from NEMA, EPA's Final Risk Evaluation contains a determination of unreasonable risk to workers for the COU relevant to this analysis, based on EPA's comparison of risk estimates for non-cancer effects to a certain benchmark (Margin of Exposure or "MOE"). As Table 1 (see Appendix) illustrates, EPA found that industrial and commercial uses of NMP as a solvent for cleaning or degreasing present an unreasonable risk of injury to the health of workers by way of non-cancer effects from (1) *acute* (developmental) inhalation and dermal exposures at the *high-end* scenario and (2) *chronic* (reproductive) inhalation and dermal exposures at the *central tendency* and *high-end* scenarios—even when assuming use of PPE. EPA used conservative assumptions for its central tendency and high-end modeling scenarios (*e.g.*, assuming 4 and 8 hours of continuous contact with NMP).

There were no unreasonable risk findings under this COU for occupational non-users.[20] EPA based its unreasonable risk determination on the comparison of risk estimates for non-cancer effects to the benchmarks as well as other considerations, including health effects of NMP, exposures from the COU, and uncertainties in the analysis. Exposure parameters for inhalation, vapor-through-skin, and dermal exposures all were assessed by running

[16] The mandate to evaluate both hazard and exposure is stated repeatedly throughout the Lautenberg Chemical Safety Act.
[17] NEMA Comments on Draft NMP Risk Evaluation, at 1, https://beta.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0047.
[18] *Id.* at 2.
[19] Systematic Review Supplemental File: Data Quality Evaluation of Environmental Release and Occupational Exposure Data, pp. 209 and 638, https://www.epa.gov/sites/production/files/2020-12/documents/5._nmp_sr_supplemental_file_data_quality_evaluation_of_environmental_release_and_occupational_exposure_data.pdf.
[20] EPA defines occupational non-users ("ONUs") as "workers who do not directly handle NMP but perform work in an area where it is used."

physiologically based pharmacokinetic ("PBPK") modeling. EPA's self-rated overall confidence for the exposure scenarios for this COU was medium.

In other COUs evaluated in the NMP risk evaluation, EPA ran "what-if" scenarios based on data that certain industries provided to the agency. From our experience, we found that the data provided and subsequently used to run these "what-if" scenarios is data based on *actual* exposure times and PPE use for specific COUs rather than EPA's conservative, unrealistic assumptions for the PBPK modeling conducted for other COUs. There were no "what-if" scenarios run for the "industrial and commercial use as a solvent (for cleaning and degreasing) in electrical equipment, appliance and component manufacturing." Therefore, as confirmed by our review of the administrative record, it appears that EPA did not run its model applying actual use data specific to the wire magnet industry.

Although this analysis focused on only one of the 26 COUs identified by EPA, we trust that the issues identified here extend to the other COUs as well.

NEMA and its Members have provided substantial additional data to EPA in these comments. We expect EPA to use this information to conduct reasonable and appropriate modeling to make a determination that NMP does not pose 'unreasonable risk' in the COUs for which NEMA Members have provided data. This is important not only for the issue at hand, but also to set an appropriate precedent as EPA considers promulgating future rules for other chemicals.

EPA Must Grant a Critical Use Exemptions

Criteria for a Section 6(g) Critical Use Exemption

If EPA is unable to change its risk determination to find that NMP does not pose 'unreasonable risk' in the articles and COUs detailed in these comments, then we urge the Agency to provide a Critical Use Exemption. NEMA understands that EPA has certain statutory obligations under amended TSCA, however, the Agency has discretionary authority as well. We herein explain how EPA can meet its legal obligations while still providing manufacturers with an ability to obtain compliance without undue burden. Under TSCA Section 6(g)(1), the EPA has the authority to grant an exemption from a risk management rule if the Agency finds that:

> (A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;
>
> (B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or
>
> (C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

It is clearly the case that:

- Use of NMP in electroindustry manufacturing substantially benefits health and public safety;
- a ban on NMP in electroindustry uses would significantly disrupt the national economy and essential functions across multiple lines of critical infrastructure; and
- use of NMP in electroindustry manufacturing is a critical or essential use for which no technically feasible safer alternative is currently available.

Imposing this ban upon US manufacturers therefore could render them less competitive in the global marketplace and threaten US-based jobs. Therefore, NEMA requests that EPA use its authority under TSCA Section 6(g) to grant critical use exemptions for electro-industry uses of NMP.[21,22]

NMP Is Essential for Use in Electroindustry Manufacturing

As we have shown, many complex, high-value products and services are provided from the use of NMP, which is essential to the manufacturing process and in incorporation into articles or products.[23] As explained in an earlier section, NMP is the major solvent and diluent used in high-performance magnet wire, which in turn is incorporated into many critical end uses. Products manufactured through the use of NMP provide substantial benefits to nearly every major manufacturing sector in the nation including transportation, energy, communications, defense, and healthcare.

The presence of NMP in electroindustry components ensures that the parts perform appropriately and contribute to product safety. Without NMP (or an effective alternative, yet to be identified), many products and processes would not function as intended and would experience a decrease in performance and safety. Thus, simply eliminating NMP from these uses is not an option for these manufacturers.

Use of NMP in Electroindustry Manufacturing Substantially Benefits Health and Public Safety

Products manufactured through the use of NMP provide substantial benefits to health and public safety. These products stem from and support nearly every major manufacturing sector in the nation including transportation, energy, communications, defense, and healthcare.

The healthcare industry has a clear connection to 'health and public safety.' Many life-saving medical devices depend on the unique properties NMP provide in electroindustry manufacturing. As explained in detail earlier, electroindustry manufacturers use NMP extensively in the production of magnet wire. Magnet wire is a vital component of transformers, motors, and generators which are widely used through nearly all industries, including healthcare. Magnet wire constitutes part of the necessary infrastructure for hospitals, laboratories, and other medical facilities.

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[21] EPA-HQ-OPPT-2019-0080-0037; See also OMB meeting documentation: EPA-HQ-OPPT-2019-0080-0036.
[22] For full list of exemptions requested, please see Table 3.
[23] Please see the "Typical NMP Uses in the Electroindustry" section of these comments for more information.

NMP is found in multiple solvents that are used in the electronics industry, some of which are specifically formulated for use with semiconductors. Semiconductor-enabled equipment such as magnetic resonance imaging (MRI) machines, pacemakers, blood pressure monitors, chemistry/blood gas analyzers, and bedside and wireless patient monitors save lives every day. In addition, precision small-diameter magnet wire is used in implantable and single use medical devices.

But other industrial sectors provide important aspects of public safety also. NMP in the electroindustry also contributes to public safety through its use in a wide range of essential communications applications. Magnet wire makes possible a wide range of communications applications such as coils in computers, telephones, cell phones, monitors.

Many electroindustry components perform as designed and contribute to product safety because of the presence of magnet wire coated with enamel based on NMP. The enamel on the wire is cured which makes it essential in safety devices because of the dielectric performance characteristics. The enamel on the wire is cured which makes it essential in safety devices because of the dielectric performance characteristics. This wire is used in the development of the dielectric performance characteristics required by national current standards.[24] The thermal fortitude of this magnet wire's coating makes it a requirement in military and aerospace applications.[25] Without NMP the product would not function as intended and would experience a decrease in performance and safety. Using a magnet wire that does not meet the standards achievable with NMP could result in failures of electrical and electronic components. Failures can have serious safety consequences for the public, including fire hazards.

NMP is also essential lighting applications. The lighting industry relies on NMP for industrial and commercial use in in paint additives and coating additives.

Battery anodes require NMP as well. NMP is used to coat the electrode plates in lithium-ion batteries.[26] It is clear that lithium ion batteries are essential to "electrification of our automotive fleet, diversify energy sources for transportation, and enable a large amount of grid scale energy storage for a higher penetration of intermittent renewable energy supply."[27]

It is important to note that among all of these applications NEMA is not aware of a known or expected risk of NMP exposure to end-users under normal COUs.[28]

A Ban on NMP Would Disrupt the National Economy

As described above, NMP is a critical component in numerous electro-industry products and systems that contribute to public health and safety. Collectively these constitute a vital part of the economy, at all levels, in the healthcare, communications, aerospace, and national defense

[24] Magnet wire must meet conformance standards through the UL 1446 performance evaluation.
[25] MW35 /76 magnet wire represents the greatest amount of magnet wire produced in the US.
[26] Claus Daniel, "Lithium Ion Batteries and their Manufacturing Challenges," Frontier of Engineering; Reports on Leading-Edge Engineering from 2014 Symposium (2015), https://www.nap.edu/read/18985/chapter/11.
[27] *Id.*
[28] Please also see "NMP Does Not Pose Unreasonable Risk" section of these comments.

sectors. Domestic and foreign manufacturing would be substantially disrupted by a ban on use of NMP in manufacturing facilities, given the current lack of technically feasible alternatives.

According to a recent report by Grand View Research, Inc., the global magnet wire market size is anticipated to reach $33.0 billion by 2025.[29] This represents a revenue-based compound annual growth rate (CAGR) of 3.7%.[30] According to Global Industry Analysts, Inc., the magnet wires market in the U.S. is estimated at $7.2 billion for 2020.[31]

It is clear that restrictions on the use of NMP ***in the magnet wire industry alone*** would cause a major disruption to our nation's economy. NEMA Members comprise the bulk of this market and their companies would be severely impacted by an inability to obtain NMP.

To obtain current, specific data on the extent to which a ban on NMP would disrupt NEMA Member businesses, and consequently the national economy, NEMA undertook a comprehensive survey of its Members.[32] The results of the survey are summarized in Table 2 (see Appendix).

In conclusion, a ban on NMP products and uses would disrupt the national economy at a time when our nation's manufacturers are already struggling with other supply chain disruptions and economic hardships due to the recent pandemic. Now is the time for the federal government to initiate actions to support businesses and foster economic recovery, rather than impose unnecessary burdens.

*No **Technically** Feasible Safer Alternative to NMP Is Available*

No technically feasible safer alternative to NMP for use in electroindustry manufacturing is currently available. Due to the unique characteristics of this chemical, no other substance has been shown to meet the rigorous standards applicable to these applications.

For example, NMP is one of the only solvents commercially available that can dissolve and keep in solution polyamide-imides (PAI) and polyimides (PI) resins (polymeric oligomer). These resins are high-performance polymers that have the high-temperature strength and strong chemical resistance necessary to make enamel. The PAI resins provides the thermal fortitude of the most common high-performance magnet wire produced in the US.[33] PI resins are used as the single coat to produce another common high-performance magnet wire.[34] Without these polymer types, magnet wire cannot reach the necessary operation temperatures above 180°C.

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[29] Grand View Research, Inc. report, "Magnet Wire Market Size, Share & Trends Analysis Report By Material (Copper, Aluminum), By Product (Round, Flat), By End Use (Energy, Automotive, Industrial, Residential), By Region, And Segment Forecasts, 2019 – 2025," Dec. 2019, https://www.grandviewresearch.com/industry-analysis/magnet-wire-market.

[30] *Id.*

[31] Global Industry Analysts, Inc. report, "Magnet Wires - Global Market Trajectory & Analytics," April 2021, https://www.researchandmarkets.com/reports/5302597/magnet-wires-global-market-trajectory-and.

[32] NEMA surveyed its Members between May 24, 2021 and June 2, 2021. To protect Member companies' confidential business information (CBI) and to address any antitrust concerns, the results of this survey were aggregated and anonymized.

[33] MW35 /76 magnet wire represents the greatest amount of magnet wire produced in the US.

[34] PI resins are used as the single coat to produce MW16.

There are alternatives to NMP used for non-magnet wire applications, but these potential substitutes are not necessarily safer. Solvents used with PAI and PI chemistry to dissolve resins have been found to be more toxic than NMP. The chemical structure of these alternatives is so similar to NMP that its use may simply create the same concerns associated with NMP. It is the nature of chemicals that by their structure and consequently, their function, risks and benefits are likely bound within any proposed alternative chemical. In the past, for instance, the magnet wire industry used dimethyl formamide as a solvent, which was then replaced, ironically, by NMP.

For these reasons, no NEMA Member has begun the lengthy process for validating the suitability of finding and substituting another chemical for NMP in electroindustry manufacturing.[35]

*No **Economically** Feasible Safer Alternative to NMP Is Available: Economic Considerations for **Finding** a Feasible Alternative*

TSCA Section 6(g)(1) directs EPA to consider whether a "technically and economically feasible safer alternative is available." In addition to our comments above about the lack of a technically feasible alternative, we also wish to provide EPA with information on economic feasibility, both in finding an alternative and implementing an alternative. Substantial costs would be incurred to conduct an adequate alternatives analysis. Such costs might include those for performance testing and additional information gathering to fill data gaps and ensure an informed decision. If no viable alternatives are readily identified, producers must invest in research and development of new chemistries, with subsequent process development and scaling up necessary to evaluate feasible options.

Estimates for conducting evaluations of alternative technologies range from the hundred thousand-dollar range (with minimal new data acquisition) to several million dollars (if the evaluation requires extensive testing and acquisition of data). The EPA is aware of the enormous expenses required to evaluate chemicals. The Agency's *initial* fee for a manufacturer-requested risk evaluation on a single chemical included requires a $1,250,000 up-front payment; full costs are undoubtedly much higher.[36]

Furthermore, if no viable alternatives are readily identified, the next likely step may be to invest in exploring entirely new technologies.

*No **Economically** Feasible Safer Alternative to NMP Is Available: Economic Considerations for **Implementing** a Feasible Alternative*

The expense imposed on companies – small and medium-sized enterprises as well as large, multinational corporations – affected by a ban on the use of NMP would be substantial enough to disrupt the market and impact the national economy.[37] Implementation costs include manufacturing infrastructure redesigns, inventory loss, new formulation acquisition costs, product redesign costs, and many other expenses—both foreseeable and unforeseeable.

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[35] Please also see "Need for Sufficient Time to Find and Implement Alternatives" section for more information.
[36] https://www.epa.gov/tsca-fees/tsca-fees-table.
[37] Please see the "A Ban on NMP Would Disrupt the National Economy" section of these comments for more information.

Even simple chemical substitutions can be very expensive. A great example is the process of substituting other chemicals for methanol in windshield washer fluid in Finland. The ECHA Committee for Socioeconomic Analysis (SEAC) reported this cost as $4 million dollars.[38] More difficult substitutions can quickly run into the tens of millions of dollars.[39]

Manufacturing facility redesign costs tend to be incredibly costly. Introducing a new chemical into the manufacturing process would result in "retooling" the manufacturing infrastructure as an unavoidable by-product of implementing new technology. These major changes require sufficient capital investment. Employees would need training.

Furthermore, disruptions in production schedules to engage in parts reformulation and conducting testing to meet safety standards would have adverse downstream impacts and possibly broader repercussions across related markets. This process could shut down a whole industry in the US making our nation completely reliant on imports, consequently causing sharp cost increases for domestic manufacturers. That in turn could cause the decimation on important manufacturing sectors of the nation, including healthcare, communications, energy, transportation, and defense.[40]

Due to the complex nature of the production process, product reformulations or facility redesigns can be extremely costly and can easily run in the tens of millions of dollars.

Exemption Period, If Required, Should Provide an Eight-Year Phase-Out

Recent EPA rulings have set a precedent for providing manufacturer exemptions to chemical bans that do not have a time limit.[41] However, if the EPA determines that exemptions granted must sunset, the Agency is required under TSCA Section 6(g)(3) that the period of exemption must be "reasonable." Therefore, if EPA chooses not to provide permanent relief in the form of the requested exemption, we expect the Agency to use its discretion to allow for an eight-year phase-out period to provide reasonable time for affected entities to comply with any final rules.

The statute provides additional support for this request. TSCA Section 6(d) states that the Administrator shall, "specify mandatory compliance dates for the *start* [emphasis added] of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule…" and furthermore states the Administrator shall "specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and provide for a *reasonable transition period* [emphasis added]."

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[38] https://echa.europa.eu/documents/10162/cc415549-cac9-4784-97dc-2170d0bf8f25.

[39] For example, see costs for substituting another chemical for BPA in thermal paper as reported by the ECHA Committee for Socioeconomic Analysis (SEAC), https://echa.europa.eu/documents/10162/7f8d2988-fad4-4343-bef3-4518336db109.

[40] Please see the "Use of NMP in Electroindustry Manufacturing Substantially Benefits Health and Public Safety" section of these comments for more information.

[41] 86 Fed. Reg. 894, January 6, 2021, "Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)", https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0080-0588.

Therefore, EPA has the authority to provide five years for the start of any ban or required phase-out of any chemical, and further allow for a reasonable amount of time for manufacturers to transition to alternatives.[42] Therefore, we expect EPA to grant eight years to allow manufacturers a reasonable time period for addressing this complex issue.

Further, there is global precedent for allowing reasonable phase-out periods for complying with chemical bans. NEMA notes that the European Union's "RoHS Directive"[43] allows for several years for manufacturers to eliminate substances that are being restricted. For example, the most recent RoHS II Amendments under Directive 2015/863 provided for four to six years to implement restrictions. EU Directive 2015/863 was issued June 4, 2015 with an effective date of July 22, 2019 for most product sectors, and an effective date of July 22, 2021 for medical devices and monitoring and control equipment.

Moreover, European authorities routinely have granted "exemptions" to the RoHS thresholds for restricted substances in designated uses. The maximum time allowable under the RoHS Directive for such exemptions extends to seven years for certain categories of products. The European authorities recognize the complexities of the chemical management process and accordingly grant sufficient time for affected entities to implement change. EPA should follow precedent, as well as their own statutory authority to grant a reasonable phase-out period of eight years. This time will allow manufacturers to determine the presence of NMP throughout its supply chain and manufacturing processes, find a suitable alternative, and implement the alternative.

Determining the Presence of NMP in the Supply Chain and in the Manufacturing Processes

The modern network between a company and its suppliers to produce and distribute a specific product consists of a global, nonlinear, multi-tiered supply chain. The system is vastly broad and complicated and includes levels starting with the raw materials supplier, moving on to a material formulator, to an article producer, to a component assembler, to an end producer, and to, finally, an original equipment manufacturer. And the network is not linear as portrayed in this simple example and is instead a complicated web of dealers, contractors, and sellers at any one tier in the chain. Further, suppliers can be found in any country throughout the world—often a product crosses many national borders several times before ultimately reaching a US consumer.

To comply with a chemical regulation, NEMA Members must first navigate the complexities of the international supply chain to determine the presence of a chemical in their supplier network. Next, they must determine the presence of a chemical in their manufacturing processes. When EPA does not provide a *de minimis* exemption, this process must be conducted for even trace amounts of a chemical, even for those that are not added intentionally. To do so, there must be reliance on the accuracy of reporting from every supplier throughout the entire supply chain. It can take months to get responses from suppliers deep within the supply chain.

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[42] Please see the "Finding a Technically and Economically Feasible Safer Alternative" and "Implementing a Technically and Economically Feasible Safer Alternative" segments of these comments for detailed information about why the electroindustry requires the maximum time allowable under the law.

[43] DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Manufacturers must devote considerable manpower and divert resources from other immediate activities to comply with an unnecessarily and artificially short regulatory timeframe. It is almost impossible to get internal approval to divert time and money towards this endeavor in advance of an actual ban. Businesses cannot proactively begin this process for hundreds or even thousands of chemicals that might someday be banned. And EPA must recognize that although these comments focus on NMP, manufacturers are also dealing with all the other TSCA Work Plan chemicals as well as other chemical regulations from international treaties to local ordinances. Small businesses are especially disadvantaged.

A process must be developed to track and manage chemicals throughout the entire supply chain to ensure compliance beyond any regulations' effective date. NEMA is actively working with its Members to support their development of materials management processes, including starting a new NEMA Materials Management Council.[44] And although some NEMA Members have robust internal processes, many domestic manufacturers have not begun to develop that level of sophistication in materials management.

A conservative estimate is that the process of determining a chemical's position in the supply chain and developing a tracing program to ensure continued compliance would take at least 6-24 months to achieve. Clearly, an immediate ban on NMP will not allow manufacturers to undertake proper review of their supply chains to adequately ensure compliance.

Finding *a Technically and Economically Feasible Safer Alternative*

Because no technically feasible safer alternative for NMP in electroindustry manufacturing is currently available, manufacturers would need to identify an immediate substitution of alternate formulations for companies to maintain production. But finding a suitable chemical requires significant investment of time and resources, with no guarantee of success within a planned timeline.

To find a substitute chemical, a conservative estimate of time to complete a *preliminary* screen for possible alternatives to NMP is four to six months, and possibly much longer depending on the complexity of the product. A more in-depth alternatives analysis including stakeholder surveys to collect additional information on safety, performance, and economic feasibility could take at least 6 to 12 months.[45]

Based on our experience, an additional one to two years to conduct adequate performance testing is needed before manufacturers can commit to using a particular alternative. This step brings the entire process of finding a suitable alternative to a total timeline of two to three years, if not longer.

[44] https://www.nema.org/directory/nema-councils/materials-management-council.

[45] For more information about the complexities of a chemical alternatives analysis, please see the California Department of Toxic Substances Control (DTSC) 302-page guide: https://dtsc.ca.gov/wp-content/uploads/sites/31/2016/01/AA-Guide-Version-1-0_June-2017.pdf.

Implementing *a Technically and Economically Feasible Safer Alternative*

Once an alternative formulation has been identified, additional time is needed for implementation. A conservative estimate of the time needed for to implement an alternative to NMP is three to five years. The process requires redesigning and testing new parts that contain NMP alternatives for compliance with applicable standards – a resource-intensive and time-consuming process. Similar tests and evaluations likely would be needed to eliminate NMP use in industrial machinery. Sufficient volume of the alternative formulation would need to be made available in the market to meet demand. Given that NMP is used in multiple electroindustry applications, these activities would disrupt and delay production schedules.

Specific tasks required to phase out existing products and introduce alternatives typically include:

- Procurement of appropriate substitute components
- Compliance assessments
- Quality assessments and certifications
- Safety assessments and certifications
- Supplier coordination
- Manufacturing modifications
- Shipment, import, and distribution

EPA Must Grant Additional Exemptions

In addition to an exemption to a ban on NMP, the electroindustry asks that EPA provide additional relief through four additional exemptions. NEMA asks EPA to provide *de minimis* exemptions for articles containing less than 1.0% (by weight) of NMP, replacement parts exemptions, large-scale manufacturing equipment exemptions, and an inventory "sell through."

EPA Must Grant De Minimis Exemptions

Due to the complexities of the international, multi-tiered supply chain, determining a presence below the threshold of 1.0 % by weight is nearly impossible.[46] Manufacturers must rely on the accuracy of reporting from every supplier throughout the entire supply chain on trace amounts of a chemical, even those that are present unintentionally. There is little, if any, evidence to suggest that the presence of trace amounts of a chemical in an article can contribute to *exposure*, which must be considered in any risk determination. Furthermore, there has been much scientific debate over whether it is actually possible to achieve 100% confidence in any formulation.
Lastly, and possibly most importantly, the EPA has precedent for providing *de minimis* exemptions.[47] The de minimis exemption allows covered facilities to disregard certain minimal concentrations (0.1% or below) of chemicals in certain situations. Although this exemption is limited, it shows that the Agency understands the difficulties associated with tracking and

[46] Please see the "Determining the Presence of NMP in the Supply Chain and in the Manufacturing Processes" section of these comments for more information.
[47] 40 CFR §372.38(a), https://ofmpub.epa.gov/apex/guideme_ext/f?p=GUIDEME:GD-TITLE:::title:deminimis.

managing chemicals below this threshold. Therefore, we urge the EPA to extend that relief to this application as well. Not having a *de minimis* exemption puts an unreasonable burden on manufacturers and therefore, EPA should provide permanent regulatory relief.

EPA Must Grant Replacement Parts Exemptions

Another exemption the EPA should provide relates to replacement parts. Many manufacturers are required to maintain replacement parts for years to ensure that consumers' products can continue to remain operational and meet warranty demands. It is not economically feasible for manufacturers to redesign and produce replacement parts years after they were originally made, because many of these parts that are no longer being actively manufactured. So that companies can meet legal and consumer requirements, we request that EPA provide a fifteen-year exemption for all replacement parts.

EPA Must Grant Large-Scale Manufacturing Equipment Exemptions

EPA should also exempt large-scale manufacturing equipment. This is equipment that exists at manufacturing facilities that does not enter into commerce, is often legacy equipment, and provides essential functions for which there is no known replacement. Existing equipment should not need to meet new compliance requirements. Accordingly, replacement parts for such equipment should also be exempted.

EPA Must Grant a Three-Year "Sell Through" Period

Finally, EPA must provide manufacturers with a reasonable "sell through" period. Manufacturers may have millions of dollars' worth of inventory through products that have already been manufactured that contain NMP, through machinery that has already incorporated the chemical, or in already purchased NMP meant to be used for production. Due to the economic burden associated with losing this inventory (small business being especially harmed), we ask EPA to provide a three-year "sell through" period to allow manufacturers to deplete current inventory.

Partnership Needed for Effective Chemical Management

EPA has undertaken efforts to reach out to and engage the regulated community, such as convening workshops and disseminating information and updates. However, NEMA proposes that a formal government-industry council be established, similar to those found in other areas of government. This would provide an ongoing opportunity for regulators and regulated parties to confer as issues develop. EPA and manufacturers could work together to find reasonable, workable solutions to the challenge of balancing jobs and the economy while ensuring chemicals are managed appropriately for human health and the environment.

The decisions made during this formative period will set the precedent for years and perhaps decades to come. To ensure the smoothest path forward for all affected parties, the agency, and other stakeholders, we need to work together now.

Conclusion

By meeting with us on March 10, 2021, EPA showed its commitment to working with all interested parties to ensure any proposed Risk Management rule will be both protective and practical. Therefore, we count on EPA to provide the regulatory relief we have requested:

1. Use the information we provided on exposure and the Agency's data analysis process to change its risk determination accordingly to a finding of 'no unreasonable risk' in the articles and uses detailed in these comments;
2. In the absence of changing its risk determination, provide a Critical Use Exemption which includes an eight-year phase-out period;
3. Grant 1.0% (by weight) *de minimis* exemptions, replacement parts exemptions, large-scale manufacturing equipment exemptions, and a three-year inventory "sell through" period;
4. Increase partnership activities with the private sector; and
5. Set appropriate precedents for future rulemakings.

We would like to request a meeting with you to discuss this matter further at your earliest possible convenience. Please contact Stacy Tatman (Stacy.Tatman@nema.org) to make arrangements.

Sincerely,

Philip A. Squair
Vice President, Government Relations

APPENDIX

Table 1. EPA NMP Exposure Scenarios

Exposure Scenario	Exposure Level/PPE	Exposure Level	Exposure duration	Acute Unreasonable Risk?	Chronic Unreasonable Risk?
Capacitor, Resistor, Coil, Transformer, and Other Inductor Mfg.	Gloves PF 5	Central Tendency	4 hours	No	**Yes**
	Gloves PF 5	High-end	8 hours	**Yes**	**Yes**
	Gloves PF 10	Central Tendency	4 hours	No	**Yes**
	Gloves PF 10	High-end	8 hours	**Yes**	**Yes**
	Gloves PF 20	Central Tendency	4 hours	No	No
	Gloves PF 20	High-end	8 hours	No	**Yes**

Table 2. Aggregated NEMA Member Data Showing Impact of a Product or Use Ban of NMP

Impact of NMP Product or Use Ban	% Range
As % of Total Products	20-75
As % of Automotive Segment	18-35
As % of Industrial Segment	8-22
As % of Commercial & Residential Segment	4-78
As % of Energy Segment	8-45

Table 3. Summary of Exemptions Requested

Summary of Exemptions Requested			
Article/Product	**Article/Product Description**	**Processing**	**Use**
Magnet Wire		• Incorporation into a formulation, mixture or reaction product in multiple industrial sectors • Incorporation into articles as a	• Industrial and commercial use in paint additives and coating additives not described by other codes in computer and electronic product manufacturing in electronic parts manufacturing

		solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing	• Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing
Insulating Material Resin		• Incorporation into a formulation, mixture or reaction product in multiple industrial sectors • Incorporation into articles in other sectors, including in plastic product manufacturing	
Motor		• Incorporation into articles as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing	
Lighting			• Industrial and commercial use in in paint additives and coating additives not described by other codes in multiple manufacturing sectors
Industrial Automation/Servo		• Incorporation into a formulation, mixture or reaction product in multiple industrial sectors • Incorporation into articles in lubricants and lubricant additives in machinery manufacturing	• Industrial and commercial use in paints, coatings, and adhesive removers • Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation • Industrial and commercial use in paint additives and coating additives not described by other codes

		• Incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing	in computer and electronic product manufacturing in electronic parts manufacturing • Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing • Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant adhesives, and two-component glues and adhesives including some resins
Battery Anode		• Incorporation into articles as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing	